Iowa Department of Public Health Division of Acute Disease Prevention & Emergency Response Immunization Program

Vaccines for Children Program Vaccine Restitution Policy November 1, 2011

Effective November 1, 2011, the Iowa Immunization Program will implement the following vaccine restitution policy as mandated by the Centers for Disease Control and Prevention, Vaccines for Children Program requirements.

The purpose of this policy is to establish requirements for VFC Program providers to replace, at the provider expense, VFC vaccine that is unaccounted and wasted (expired, spoiled or improperly stored) due to negligence on behalf of the provider. This policy is intended to address instances of extreme/on-going negligence resulting in the wastage of VFC vaccine.

Restitution Process

1. The Iowa VFC Program will review incidents of vaccine wastage to determine if restitution will be required. Restitution will be required for negligent provider activities or recurring issues that result in vaccine wastage.

Situations that may require provider restitution (this list is not comprehensive)

- Storage and handling errors resulting in vaccine wastage.
- Provider fails to act according to the agency/practice's Emergency Vaccine Storage and Handling Plan.
- Situations resulting in re-vaccination due to either improper vaccine administration or improper vaccine storage and handling resulting in the administration of non-viable vaccine. The provider may be responsible for purchasing private vaccine to revaccinate VFC eligible children.
- Excessive vaccine ordering leading to overstock resulting in vaccine wastage.
- o Ordering combination vaccines which results in wastage of single antigen vaccines.

Situations that may not require restitution (this list is not comprehensive)

- A package not delivered to the provider in a timely manner or is otherwise damaged or exposed to improper temperatures during transit.
- A provider experiences a refrigerator/freezer malfunction, and the contracted alarm company does not notify the provider. The clinic should document the event and include a plan to prevent this from occurring in the future.
- Power is lost due to inclement weather or natural disaster.
- o A vial is accidentally dropped or broken by a provider.
- Extraordinary situations, not listed above, deemed by the Iowa VFC Program to be beyond the provider's control.

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- 2. When restitution is required, the provider will receive notification from the Iowa VFC Program detailing the number of vaccine doses requiring restitution.
 - The invoice will detail the number of doses by vaccine manufacturer, type, and presentation (vials, syringes).
- 3. The provider will be responsible to purchase vaccine equivalent to the notification received from the Iowa VFC Program. The vaccine shall be replaced within 30 days from the date of the notification unless mutually agreed upon by clinic staff and VFC program staff. The replenished vaccine shall be placed in VFC inventory and used to vaccinate VFC eligible children.
- 4. The privately-purchased vaccine shall consist of the same manufacturer, type, and presentation of vaccines identified for restitution by the Iowa VFC Program.
 - Substitutions for vaccine manufacturer and presentation must be agreed upon by clinic staff and Iowa VFC Program prior to purchasing the vaccine.
- 5. A copy of the packing slip for the privately purchased vaccine shall be faxed to the Iowa VFC Program at 1-800-831-6292 attention VFC Program Coordinator.
- 6. Failure to comply with the restitution policy will result in the clinic being suspended from the VFC Program. Clinics on suspension will not be able to order VFC vaccine until vaccine has been replaced.
- 7. Failure to replace wasted VFC vaccine within 30 days of the clinic being placed on suspension will result in the clinic being terminated from the VFC Program. The provider may be permitted to re-enroll after the replacement of wasted VFC vaccine. Re-enrollment will be at the discretion of the Iowa VFC Program.
- 8. Providers who fail to comply with the Vaccine Restitution Policy will be referred to the Iowa Department of Human Services, Medicaid Program for further investigation of fraud and abuse.

Procedures to Minimize Vaccine Loss

Health care providers should implement and adhere to the following items to minimize vaccine loss:

- o Provide adequate vaccine storage and monitor storage conditions.
- Do not over-order or stockpile vaccine.
- Never assume vaccine is nonviable in the event of a storage problem. Contact the lowa VFC Program immediately for instructions.
- Conduct count of vaccine inventory at least monthly.
- Check vaccine expiration dates at least monthly.
- o Rotate vaccine stock regularly; move earliest expiration dates to the front.
- Report vaccine that will not be used and will expire within 2-3 months to the Iowa VFC Program.